Moderator: Melissa Shapiro March 24, 2015 1:00 pm CT

Coordinator:

Welcome and thank you for standing by. At this time all lines will be on listen-only mode until the question-and-answer session of today's call. At that time it is star-1 from your touchtone phone to ask a question, star-2 to withdraw the question.

Today's call is also being recorded. If you have any objections please disconnect. I'd like to introduce Melissa Shapiro. You may begin.

Melissa Shapiro: Thank you, Robin. Good afternoon everybody from Atlanta, Georgia. My name is Melissa Shapiro and I work with the outreach team in CDC's Emergency Operations Center. I'm so pleased to welcome you all to today's call. This is the fourth in a call series to partner with you all, the members of the West African community in the United States.

> Today's call will focus on the Ebola prevention vaccine study in Sierra Leone and we're thrilled to have Alison Albert from CDC with us. We'll hear a presentation from Ms. Albert before opening the lines for your questions and comments.

We've had some great questions on the previous calls and have learned about some of the concerns among the members of the West African community. And we're hoping to have the same level of participation from you all today. If you have any questions about today's topic, suggestions for future topics, or

just want to provide us with some feedback, we'd love to hear about it.

There are a couple of ways for you to do that. You can always email us at EmergencyPartners@CDC.gov - that's E-M-E-R-G-E-N-C-Y - P-A-R-T-N-E-R-S at C-D-C dot Gov. And please feel free to email us right now with any questions that you have for today's speaker.

Another way to talk to us is by joining these conference calls and ask us questions or tell us about what you're hearing in your community or share a story with us. The Operator will tell us how to do that later on in the call.

Before we get to today's primary topic we'd like to share a brief update on the Ebola outbreak and response. As of March 20, 2015 there have been almost 25,000 suspected, probable, or confirmed cases of Ebola reported to the Ministries of Health, including over 800 cases among healthcare workers and almost 10,300 deaths.

The response strategy has successfully avoided the worst case scenarios predicted by many people at the beginning of the response.

In Liberia, there has been concerted effort by Ministries of Health, NGOs, WHO, CDC, and others to get back to zero. Over 100 contacts have been traced. CDC and Liberia are also focusing on longer-term needs and expansion of global health security goals such as surveillance system, training needs, and transition of in-country emergency operation center.

Sierra Leone continues to have new cases of Ebola particularly in the Port

Loko and western areas. CDC's goal is to continue to push to zero.

In Guinea, we continue to see new cases. There have been three recent

infections among healthcare workers in hospitals and CDC is working with in-

country staff to enhance surveillance, lab testing, testing of bodies, and social

mobilization activities.

Additionally following CDC Director Dr. Tom Frieden's trip to Guinea a few

weeks ago, he would like to encourage members of the Guinean diaspora in

the US who are medical professionals to volunteer to support the Ebola

response in Guinea. If there are medical professionals who are members of the

Guinean diaspora on this call who would like to volunteer in Guinea we

encourage you to email us at EmergencyPartners@CDC.gov.

And so with that, let me introduce you to today's speaker and let's get started.

Today's speaker is Ms. Alison Albert. Ms. Albert completed her

undergraduate degree in biology at Tufts University. After receiving her

bachelor of science, she received her master of public health in behavioral

science and health education from Emory University.

While completing her MPH she began working at the CDC in Atlanta on the

Get Smart Know When Antibiotics Work program and continued working

with that program for seven years. The Get Smart program implements health

communication strategies to promote the appropriate use of antibiotics in an

outpatient setting, contributing to efforts to combat antibiotic resistance.

Following her work on the Get Smart program she became the lead health

communication specialist in 2008 for CDC's Division of Bacterial Diseases in

the National Center for Immunization and Respiratory Diseases. Ms. Albert

remains in that position where she oversees communication on a variety of

subject matters including pertussis, Legionnaire's disease, pneumonia,

meningitis, appropriate antibiotic use, and groups A and B strep among others.

Currently she is CDC's communication co-lead for the Ebola vaccine clinical

trial in Sierra Leone. Ms. Albert, please go ahead with your presentation.

Alison Albert:

Great, thank you so much, Melissa. And thank you all for calling in today. So as Melissa mentioned, I'm sharing information about an Ebola vaccine study

in Sierra Leone called STRIVE. That stands for the Sierra Leone Trial to

Introduce a Vaccine against Ebola.

Before I jump into this I want you to know that I encourage you to share this

information with people you know in Sierra Leone, especially those who

might be eligible to participate in the study.

So we're going to spend the time we have together today talking about a

potential Ebola vaccine. Right now no vaccines have been proven to protect

people from getting Ebola. But it's possible that a vaccine may help protect

people during this outbreak or future ones.

Vaccine manufacturers and public health agencies around the world are

working together to develop and test vaccines that could be effective in

preventing Ebola.

You might be hearing about two vaccines in particular that are furthest along

in development and that look promising in early testing. At this point, these

vaccines have been tested in hundreds of people in Africa, Europe, and North

America.

You can learn more about candidate Ebola vaccines from the World Health

Organization. They have information up on their website, which you can find

by Googling, "W.H.O. Ebola vaccine."

So far results from these studies are encouraging and suggest these vaccines

are safe to use in healthy individuals. That's an essential step before

progressing on to the next phases in studying the vaccine. Studying them in

large numbers of people who are at risk for getting Ebola could tell us if the

vaccines work and how well.

To be able to do this we need to study them in places where Ebola is

spreading like Sierra Leone. That's why the Sierra Leone College of Medicine

and Allied Health Sciences or COMAHS for short, the Sierra Leone Ministry

of Health and Sanitation or MoHS, and the CDC are all working closely

together to plan STRIVE.

This study is going to look at two things: if and how well one of the Ebola

vaccines in development called the rVSV-ZEBOV vaccine helps protect

people from getting Ebola; and, if that vaccine is as safe as early small studies

have suggested.

Similar studies are also occurring in other countries affected by Ebola,

including Liberia and Guinea. Those studies are using this vaccine and

another one.

CDC has a team of people in Sierra Leone that have been working with

COMAHS, MoHS, and the districts for months to help prepare for STRIVE.

Their efforts range from community engagement to facility renovation to

finalizing the study specifics and hiring and training local study staff, and

much, much more. I'll tell you more about each of those in a little bit.

That's the background info I wanted to share with you before moving on to

more of the specific details. Now I'm going to cover the measures we've

taken to get approval to conduct the study; when STRIVE is expected to start

and some of the steps we've already taken; where the study will take place

and who is eligible to participate; some specifics about the study design; and

information about the vaccine being used.

Given the urgency for an Ebola vaccine, study planners have been working

around the clock to launch STRIVE. However, as with any vaccine study,

necessary approvals must first be obtained to ensure the study meets national

and international safety and ethical standards.

In preparation for the launch of STRIVE, planners have been working to

acquire these necessary approvals. The study has been approved by the Sierra

Leone Ethics and Scientific Review Committee of the MoHS, the Sierra

Leone Pharmacy Board, and the Institutional Review Board at CDC. The US

Food and Drug Administration or FDA has also said it's safe to proceed with

the study.

Once the study is launched it will continue to be monitored by Sierra Leone

and CDC Institutional Review Boards. They will make sure the rights and

welfare of participants are protected. There will also be an independent data

and safety monitoring board that will closely monitor STRIVE.

This monitoring group has members from Sierra Leone and elsewhere who

are experts in vaccines, immunization safety, ethics, and clinical trial research.

You may be wondering when this study is starting. I'm very happy to say that

if everything goes as planned we should be able to start enrolling participants

as soon as next Tuesday, March 31. In the months leading up to this start date,

the STRIVE team in Sierra Leone has been working hard to get the logistics

ready for this study and to share information about it.

For example, buildings are being built or renovated to be able to store the

vaccine and enroll and vaccinate participants. And about 200 local people

have been hired and are being trained to conduct the study.

Study leaders continue to engage and inform leaders at the national, district,

and community levels. They are sharing information about STRIVE and

addressing any questions these groups might have. For example, parliament

has been briefed, we've met with paramount chiefs, tribal and religious

leaders, ward councilors, and elders in the study areas. And we will continue

to keep them informed about study progress.

We've also been working with health facility leaders in study areas to plan for

enrollment and vaccination including public health facilities, hospitals, clinics,

and Ebola treatment and holding units. Information has been shared with

medical, nursing, and pharmacy organizations. And we're starting to meet

with potential study participants to give them information they need, answer

their questions, and give them time to decide if they want to participate.

And last but not least, we've been working with social mobilization teams to

share information about the study. And we have plans to participate in radio

shows to reach the larger community.

So now for more details about STRIVE and where exactly it's taking place in

Sierra Leone. The study will be in all of Western area and certain chiefdoms

in Bombali, Port Loko, and Tonkolili. Those areas were chosen based on

several factors including being heavily affected by the outbreak in the past

Moderator: Melissa Shapiro

03-24-15/1:00 pm CT

Page 8

few months, having the ability to store the vaccine, and having space to both

enroll and vaccinate study participants. It's possible though that additional

study sites could be added later if more participants are needed.

Now to tell you a little more about who is eligible. We're hoping to enroll

about 6,000 people who are higher risk of getting Ebola because of their jobs.

This includes people from the Sierra Leone and people from other countries

who are working there such as doctors and nurses, health facility workers

meaning cleaning, lab, pharmacy, security, and administrative staff, as well as

burial workers, ambulance and surveillance teams, and workers responsible

for swabbing people who have died.

An important point that I need to make is that participating in the study is

completely voluntary. Deciding whether or not to participate in this study

won't have any impact on someone's ability to continue their job. No one will

be forced to participate.

And we are working with partners to ensure that those who are eligible and

their circles of influence have all the information they need to decide whether

or not they want to be in the study.

By studying people at high risk for getting Ebola, we're better able to

determine how effective the vaccine is. If this study or studies going on in

other countries show the vaccine can safely protect people from getting Ebola,

the World Health Organization and other agencies are actively planning how

to make the vaccine available quickly to affected countries like Sierra Leone.

So I know your next question will be "When will a vaccine become available

to everyone?" But we can't predict that since there are many steps that have to

be taken before a vaccine is licensed and approved for public use.

By studying the vaccine in Sierra Leone we are getting one step closer to

having a safe and effective vaccine that can be made widely available to help

protect people from getting Ebola.

I also want to go over a few more points about STRIVE and the vaccine that

will be used. The vaccine will be offered for free to study participants. Once

someone is enrolled in the study they will either get the vaccine that day or be

assigned to get it about six months later.

The timing for when someone will get the vaccine is assigned using

randomization. That means they will have an equal chance of being assigned

the early or later date, like by flipping a coin. After enrolling in the study,

participants will be called monthly to find out if their health has changed at

all.

These calls will continue until six months after getting vaccinated. A few

hundred people will be called several times during the first month after

enrollment to look even more closely at their health. All study participants

will be provided a mobile phone to be used for these calls.

So I mentioned earlier that STRIVE is using what's called the rVSV-ZEBOV

vaccine or VSV vaccine as we sometimes say for short. This vaccine was

developed by the Public Health Agency of Canada and was licensed to

NewLink Genetics Corporation and Merck. We don't yet know if this vaccine

may help protect people from getting Ebola or by how much. We also don't

know how long protection would last, if the vaccine works.

Moderator: Melissa Shapiro

03-24-15/1:00 pm CT Page 10

Although we don't know how well it may work, this vaccine is designed to

protect against Zaire ebolavirus, that's the strain causing the current outbreak

in West Africa.

Everyone who joins this study in Sierra Leone will get a single dose of this

vaccine at the same concentration. It will be given as a shot in the upper arm

and nobody will receive a placebo.

It's very important to know that the vaccine *cannot* cause Ebola. Let me

repeat that, the vaccine cannot cause Ebola. It's not possible to get Ebola from

the vaccine being studied because it does not contain the whole Ebola virus.

Only the whole virus can cause Ebola disease.

When I say it doesn't include the whole Ebola virus I mean that the vaccine

contains only a small piece of the virus, a gene. That single gene should help

the body build defenses, or antibodies, against Ebola.

This vaccine has already been studied in more than 500 people in other

countries. It did not cause any serious side effects or death in those studies. It

is also currently being studied in Liberia and Guinea.

Some of the common side effects seen so far include a sore arm, fever,

headache, or muscle ache. These side effects typically get better in about one

to two days. Less common side effects have been things like having mildly

painful joint swelling or mouth ulcers. Those typically get better in about two

weeks or less. When larger numbers of people get vaccinated, additional side

effects may be seen that we don't already know about.

Page 11

Although the vaccine cannot cause Ebola in those who get it, it's important to

know that people who get the vaccine could still get Ebola. This can happen

for several reasons, like if they were infected before getting vaccinated, if

they're exposed before the vaccine has a chance to build up protection in the

body, or if they're exposed after getting vaccinated and the vaccine doesn't

fully protect them from Ebola. As I already mentioned, it's not yet known if or

how well the vaccine works.

That is why those who get the vaccine still need to take other preventive

actions to protect themselves from getting Ebola. They should do things like

practicing good hand hygiene, wearing recommended PPEs, using properly

mixed chlorine solution to clean, being careful with needles when taking care

of patients, and not treating patients outside of health facilities. All steps

you've heard before.

As I mentioned earlier, if this study or studies going on in other countries

show the vaccine can safely protect people from getting Ebola, more vaccine

could be made and eventually offered to people in countries at risk for Ebola

outbreaks.

We're incredibly grateful to be working with our partners in Sierra Leone, the

College of Medicine and Allied Health Sciences, the Ministry of Health and

Sanitation, and the districts to conduct this important study in the fight against

Ebola.

Thanks so much for giving me this time to share today. I'm certainly happy to

answer any questions you might have. We also have Dr. Stephanie Schrag on

the line who is helping to oversee the study and she can help with your

questions too. And you can find more information about STRIVE on

ClinicalTrials.gov by searching STRIVE.

And before we open the lines for questions I was hoping I could pose a few

[questions] to you, if that's okay, to think about. First, what have you heard

from friends or relatives in Sierra Leone about this study? What else could we

do either here or in Sierra Leone to help get information out about the study?

And what are the steps you would recommend we can take if rumors start

spreading about the vaccine or the study?

And with that I will turn the call back over to Melissa.

Melissa Shapiro: Thank you so much and thank you for sharing all that very valuable information with us. I now feel like I'm much more knowledgeable about the vaccine trial in Sierra Leone.

> And now we'd like to hear about your questions, about this topic or really anything related to the Ebola outbreak. We'll start with questions related to this presentation and the vaccine trial and then we can move to ones that are more generally about the Ebola outbreak. So please ask the ones about -- ones related to the vaccine trials first.

> But before I open up the lines to hear from you, I would like to remind everyone that today's conference is being recorded and a transcript of the call will be posted online at CDC's <u>Partnering with West African Communities</u> call series webpage.

> And also in addition to Ms. Albert who just presented, we have representatives from CDC's Vaccine, Health Promotion, and Policy Teams as well as the State Department and USAID on the line available to answer your questions.

Moderator: Melissa Shapiro

03-24-15/1:00 pm CT Page 13

And with that, Operator, can you tell the audience how to ask a question,

please?

Coordinator: Yes, and thank you. At this time to ask a question please press star-1 from

your touchtone phone, unmute your line, and record your name clearly, as

prompted. To withdraw the question it will be star-2. And our first question

comesfrom Sylvie Bello. Your line's open.

Sylvie Bello: Hi, thank you so much. My name is Sylvie Bello and I'm with the Cameroon

American Council. We are a national African immigrant organization based

out of Washington D.C. with affiliates in 30 states. My question - actually my

remarks actually piggybacks on the question that was asked about how to

engage the West African community.

We had contacted Juanita Rilling and Jonta Williams of USAID about

translating, about language access, you know, how do you make this

information culturally sensitive in the middle of the day, on the week day. I'm

not sure if this is - you know, I'm sure there are many other ways in which we

can engage the community. We are currently doing our fifth annual 10-state

tour around the country starting at the University...

Melissa Shapiro: I'm sorry, Sylvie, we're having a very hard time hearing you. I think there

might be a bad connection.

Sylvie Bello: Can you hear me now?

Melissa Shapiro: Yes, a little bit better.

Sylvie Bello: Okay, well, my remarks are piggybacking on what the presenter said about

how do we reach out to the community here in the US. And that way - to get

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 14

the messages back home or when we do travel home for the summer and other

holidays. One of the ways would be to actually come out into our mosques

and to our churches.

We had reached out to US - the State Department, Jonta Williams and to

Juanita Rilling at CDI - CIDI on coming out to our churches and mosques and

have not heard back, especially around language access and translating the

information. What are your thoughts about that?

We're actually kicking off our 10-state tour today at the University of

Pennsylvania with a Penn State - with Penn African Student Association and

going up and down the East Coast, some parts of the South, and California.

So what are you working on outside of conference calls in the middle of the

day during the week, how are you making sure that you're reaching the

community in a culturally-sensitive, language-appropriate manner? Thank

you.

Stacey Hoffman: Hi, this is...

Alison Albert:

(Overlapped Speaking) So I... go ahead.

Stacey Hoffman: I was just going to say that we have Craig Manning joining us and he's with

the Health Promotion Group and I think he might be the best person to

connect you with on that question unless there's someone else on the line who

wants to go ahead and answer?

Alison Albert:

Yeah, this is Alison. I think I can obviously speak on behalf of the vaccine

information and what we're doing around that. I can't really speak to the

larger Ebola response. But we have been thinking very hard and thoughtfully

about how to really, you know, talk to people in a right way to make them

understand the trial and the risks and benefits to participating, and what it

means to participate.

And we were fortunate enough to be able to work with an in-country

organization called Focus 1000. And they were able to do a series of

formative research for us so we were able to do focus groups and in-depth

interviews with public health and medical leadership in the country as well as

potential study participants.

We were able to talk to them about their knowledge and perception around the

candidate Ebola vaccine and the trial that was going to be happening in a few

months. We were also able to show them some sample materials that we had

started to develop and try and make sure that the images we were using were

appropriate and were conveying the message that was being supported by the

text.

And then we were able to continue to work with Focus 1000 to refine those

materials and make sure that they were - what they had envisioned based on

the research they conducted for us.

We're also lucky that we are getting to work with Peace Corps language and

cultural facilitators in the country and we have a few of them that are working

full time with our CDC vaccine study there and they have just been priceless

to this response for us.

They are helping us with the language barriers that we're having and the

nuances for how we're wording things. For example, in the US we say we're

going to get a vaccine but, you know, they've been really teaching us that over

Page 16

there we're saying - it's take a vaccine or actually take the marklate, that's the

word we're using.

So we've really been trying to work very closely with the folks we have

access to in-country. We have not taken advantage of any resources like

yourself here in the United States yet, so that is certainly something that we

could look further into.

Coordinator:

And thank you. Sylvie, does that answer the question?

Sylvie Bello:

Thank you.

Coordinator:

All right, thank you. Our next question is from Earl Burrowes, your line's

open.

Earl Burrowes:

Hi, thank you very much. Just a quick question. It would be helpful to find

out what the difference is between the Ebola vaccine trial carried out in

Liberia and the one being done in Sierra Leone right now.

And the second question, follow-up to that is, are there any lessons learned in

the Liberia trial case that are transferable to Sierra Leone? And I'll take my

question while I listen.

Alison Albert:

Okay, sure, thanks, Earl. You know, I - unfortunately we don't have anyone

from NIH on today's call so I will speak about the basics that I know about

their trial and how it's different from the one in Sierra Leone.

So NIH is working with the Liberian government to conduct an Ebola vaccine

trial there as well. And some of the differences are that they - first of all, are

using two of the candidate Ebola vaccines so they are using both of those as

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 17

well as a placebo. They're doing what's called a randomized control trial so

folks will get randomly assigned through a process there to either one of the

Ebola vaccines or the placebo.

And then it's a - nobody will know what somebody's getting and then they'll

go back and look at the safety data around those vaccines and other things.

And they were just starting off with about 600 people was the goal for the first

phase of their study.

There are plans for that to grow larger last I heard. So that's one of the

differences. And then the lessons learned - one other difference is that their

trial is not just focused on health and other front line workers like ours is

focused on. Theirs is a little bit of a broader group of people that can

participate in the trial.

We have been getting some lessons learned from them, which has been

immensely helpful to us. I think one of the most important things is how

critical it is to really engage the right groups and leadership before we start the

trial.

So those were some of the things I talked about making sure we talked to

Parliament, paramount chiefs, religious leaders, really those critical groups of

folks that we really need to make sure we talk to and that they're involved in

the trial and know what's going on before we start approaching community

members across the country, that was very important lesson learned that we

got from the Liberian experience.

Earl Burrowes:

Thank you.

Coordinator:

And thank you. Our next question is from Ronke Luke. Your line's open.

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 18

Ronke Luke:

Yes, hi, thank you very much for the calls and the briefing. I may - I joined late so I may have missed some of the - you know, I missed the opening remarks so I don't know if you covered the question I have but how would you know or what are you looking for in terms of this vaccine trial in terms of success? How would you know if the trial is successful?

And then you know, sometimes if you follow these vaccine or medical trials, they get abandoned for whatever reasons. If you could speak to that, you know, the success versus a trial gets abandoned. And you know, communicating what that success would look like once the trial was over.

And then the next question I have which is not quite trials but I guess - it's not vaccines but it's treatment, there was a lot of interest at - sort of at the height of the cases as they were coming in, in blood serum therapy. And I'm not really sure - you know, lots of people trying to set up and do things related to that.

I'm not sure if that ever happened that there was any successful implementation of blood serum therapy. Is that something that occurred in any of the three countries? And as we've seen certainly in Sierra Leone and Guinea, the cases seem to be persistent.

Is that something that could be considered or would be considered because, you know, if you're sick you can't - the vaccine, I don't think [it] helps you if you're already sick so anything you can share would be appreciated.

Alison Albert:

Sure, how about - Karen, do you want to take her - Ronke's second question about the therapeutic trials first?

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 19

Karen Wong:

Sure, this is Karen Wong, I'm a member of the Clinical Guidance Team here at CDC. So regarding your second question about convalescent therapies for people who have confirmed Ebola virus disease, there are trials that are ongoing in Sierra Leone.

I think they've sort of got started at the beginning of this year. And that's about [all] the information I have on them. There aren't any results from those trials yet, but they are ongoing.

Ronke Luke:

Okay, thank you.

Alison Albert:

Okay, thanks, Karen. I think the other question you asked about the success of the trial and how will we know it's been successful, it's a really interesting question to ask. I mean, I think from our perspective and Dr. Schrag, if you have anything else to add please chime in, but, you know, what we're really looking - excuse me - to do is measure the efficacy of this vaccine and really build upon the safety profile that's already been documented for the vaccine.

Those are our end goals for this trial. And we look at efficacy by measuring rates of Ebola disease in those who are vaccinated compared to those who have not yet gotten the vaccine. And of course, safety, we're monitoring through frequent contact with the study participants and building upon that.

I mean of course we hope to not learn anything that's concerning about the vaccine regarding safety and there's been a lot of the safety data already collected but there's still the chance we could learn something else. Of course success would be great for us to, you know, have enough people enroll in the trial, that's really important that we get enough people to enroll in the trial to really help us be able to measure the efficacy of the vaccine.

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 20

So those are really important pieces to us for having a successful study here. I

don't know anything about other trials being abandoned, unfortunately.

There's no - obviously no intention of that happening here.

There are independent monitoring boards that are looking at the trial and if

there's anything concerning that they're seeing, which means that the trial

might be paused for them to review that and decide whether or not it should

continue, things like that could happen.

But there are no other reasons, you know, besides us finding out early from

our trial or others that the vaccines are fantastic and very safe, maybe that

would mean, you know, progressing and moving more quickly and possibly

stopping the trial early for that.

I think those are all in the realm of possibilities but there's no reason why this

trial would be abandoned if that's something that has happened in other trials

previously.

Ronke Luke:

Thank you.

Coordinator:

At this time I see no further questions. As a reminder, to ask a question it's

star-1 from your touchtone phone.

Melissa Shapiro: Okay, we did receive one question prior to the call via email. So I will go

ahead and read that question out loud and, Alison, I'll direct this one toward

you. But the question was in which districts is the vaccine being tested? Is it

among certain populations, higher risk, healthcare workers, etc.?

And how is consent and education being handled? Are the documents

available that are being used for education and consent?

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 21

Alison Albert:

Sure, those are great questions. I think I covered the first two in the presentation earlier but I'll go over them again. So the trial in Sierra Leone will take place in five districts, so it's Western Area Urban, Western Area Rural and then it's in certain chiefdoms in Bombali, Port Loko, and Tonkolili.

And we are targeting folks who are at higher risk of getting Ebola because of their jobs so doctors and nurses, health facility workers, cleaning lab, pharmacy, security, and administrative staff. And then also burial workers, ambulance and surveillance teams, and workers responsible for swabbing people who have passed away.

In terms of educating folks, we're doing quite a bit of things that are getting underway. This week - well, previously we'd already been out there in communities talking to leadership and parliament and folks like that. Until we had all the approvals to move forward with the study we couldn't talk to study participants yet, we couldn't start recruiting them.

So we got that approval a little while ago and now we're working on planning a series of information sessions across the study areas. So there will be about 150 or so of those sessions starting this week and that's going to be trying to get all these eligible persons to come to those sessions, hopefully at their facility or somewhere nearby.

And those will be staggered across the districts as we roll out the study and we'll be presenting there. We'll have study staff who are presenting and then they'll be going - using a special slide deck that we've put together that uses a lot of the images we've been working on to illustrate the study points and talking about the vaccine.

Moderator: Melissa Shapiro

03-24-15/1:00 pm CT Page 22

A lot of the things I told you today are part of that, so the possible side effects

of the vaccine, things like that. And then during the end of that session they'll

be given a trifold brochure that they can take home, read through that or look

at the pictures, and talk to their family or community members and have some

time to think about participating in the study.

There's that kind of material that we could share with folks who might be

interested and want an email to see that.

And then during the consent process there will be very trained people that will

be going through that consent form. And they'll be asking some questions

along the way to make sure folks are understanding what they're hearing or

reading in the consent form.

And there will be translators available in case anyone needs extra help with

English or Krio or anything like that. So we'll have folks around to help make

sure people are clearly understanding the consent form and feeling informed

about that agreement process.

Melissa Shapiro: Great, thank you so much. Operator, do we have any other questions in the

queue right now?

Coordinator:

I do not see any questions in the queue right now.

Melissa Shapiro: Okay, and I'd like to remind everybody that if you'd like to submit a question

via email, we can answer that and you just email us at

EmergencyPartners@CDC.gov. And before we open up the lines for just any

general Ebola related questions I just wanted to reiterate some of Ms. Albert's

questions that she kind of posed to the group at the end of her presentation and

see if anybody would like to answer those or discuss any of those.

But she was asking what have you heard from friends or relatives in Sierra Leone about this study? What else can we do here, either at home or in Sierra Leone to help get information out about the study?

And what are the steps you would recommend we can take if rumors start spreading about the vaccine or study? So I don't know if anybody would like to submit any answers via email or speak now about any of your thoughts about these questions?

Coordinator: And we do have

And we do have a question online here, Kim Kargbo, your line is open.

Kim Kargbo:

Hi, I'm not calling in about the questions that you just asked. I had a question and response to the answer that you just gave on the other questions first. And that is, the materials that you're using for education, are those posted online somewhere where people can access them and look at them?

And then also, is there a schedule of the - I don't remember what you call it - but the meetings where you're going to educate people on the vaccine trials. Is that schedule posted somewhere so that - well, we work in Bombali district and just to see, like, when those timeframes are going to be taking place?

Alison Albert:

Okay, so Kim, quick question, who did you say you work with, again? So you're in Bombali. That'd be good to know.

Kim Kargbo:

We work in Bombali district. We work with Makeni with Women of Hope International.

Alison Albert:

Hope International, okay. Yeah, we don't have anything posted online right now regarding the information sessions, that's something that's a little bit of a

fluid process right now as the trial gets underway. I think it would be really

helpful though to make those connections and I'm wondering if you can email

the Emergency Partner's email address and they can connect you with me.

And I think it would be really helpful if we were reaching out to folks like you

in the districts that could be impacted by these information sessions and the

trial. And I'd certainly be happy to make those connections. I think it'd make

more sense for in-country CDC folk to be able to talk to you about that.

If that sounds okay to you and then - likewise, if you put a request in about

those materials when you email, I'd certainly be happy to share those with

you. And if you do end up going to meet any of the vaccine team in-country,

they can certainly show you things in person as well.

Kim Kargbo: Right, what is the email address that you want me to write to?

Alison Albert: Sure, it's EmergencyPartners@CDC.gov.

Kim Kargbo: And what did you want me to ask in that to make sure I connect it properly?

Alison Albert: Yea, if you can just reiterate your questions that you asked about the schedule

of information sessions, you work in Bombali, and interested in seeing some

of the materials we're creating. I'll know what it's about, thank you.

Kim Kargbo: Thank you. And your name again, was what again?

Alison Albert: It's Alison Albert.

Kim Kargbo: Okay, and just to answer one of the questions you guys just posed too, like I

said, I work in Bombali district. I'm not there currently. Right now I'm in

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

4-15/1:00 pm CT Page 25

Memphis but I'll be there in a couple of weeks and I haven't heard anything

yet about vaccine trials. That doesn't necessarily mean that the word is not out

but it probably means that word's not out very far.

So that - you were asking what if people heard and I haven't heard anything

though I have a full staff on the ground and are - am there fairly frequently.

But I haven't heard anything on the ground in terms of people talking.

Alison Albert: Okay, thank you for letting us know that. We definitely - hopefully these

information sessions will get the word out further. They're starting in Western

and then moving toward the other districts so I'm not sure when exactly

they'll start in Bombali, but it will be a few weeks after Western.

Kim Kargbo: All right, thank you.

Alison Albert: Sure.

Coordinator: We do have another question from Ronke Luke. Your line's open.

Ronke Luke: I don't know if this is relevant to your dissemination of your info or not but I

was just curious, in the sort of - throughout this Ebola epidemic there are a

number of professional groups in West Africa, for example, there's the West

Africa College of Physicians and West Africa College of Nurses and a

College of Surgeons, etc.

I've never heard them mentioned at all in any of these, you know, NIH, CDC,

any of these - you know, kind of engagements. I'm just curious what - why is

that? Is it, like, neither side knows - I don't know. Have you never reached out

to them?

Moderator: Melissa Shapiro

03-24-15/1:00 pm CT

Page 26

Alison Albert:

Actually we have in Sierra Leone. I don't know if it's the same exact organizations that are maybe specific to the larger area of West Africa, but we have been working with the Sierra Leone medical and pharmacy and nursing associations there.

We've been presenting to them, the study PI in-country has met with them and talked to them about the vaccine trial. We've very much been trying to talk to them and also separately even having a special meeting for the nurse matrons and chief nursing officer and folks like that.

So we are trying to reach them but if there are other organizations that we should be aware of that are maybe more of an umbrella group in West Africa, I would love to know about that.

Ronke Luke:

Yes, I mean there is - there's a regional group called - well, there's a College of Physicians and a College of Surgeons and College of Nurses that crosses the entire - and they have an annual conference - obviously with Ebola that probably didn't happen.

So you have a big annual conference and they're involved in medical education and learning and all sorts of things, right, throughout the region.

And just was - it dawned on me when you talked about groups to engage I was like, you know, I've never heard the College of Physicians ever been mentioned in any of this. So I was just curious.

Alison Albert:

No, that's really helpful, thank you. We'll certainly look into that. I know we've been very focused on our Sierra Leone partners right now but it absolutely makes sense to reach out to a broader group so thank you.

Melissa Shapiro: And we've had a couple questions come in online so I will read those. The

first one is how many people do you hope to enroll in the trial?

Alison Albert: Sure, we are hoping to enroll 6,000 health and other frontline workers in

STRIVE, our trial in Sierra Leone.

Melissa Shapiro: Great. And then the next one is how is the study affected by the fact that the

number of Ebola cases in Sierra Leone, Liberia, and Guinea has dropped

considerably?

Alison Albert: Sure, that is a really good question. So - and of course, we are extremely

pleased to see the decreasing of cases in some areas of West Africa and really

do hope that that trend continues.

So even as Ebola cases decline this studywill still offer an opportunity to learn

more about the vaccine, which could go towards developing a better vaccine.

We hope that even as disease rates decline that people will still be interested

in participating in this study, and it will help us find ways to prevent Ebola

outbreaks from growing so large if we find a safe and effective vaccine.

And fortunately, the study design has some flexibility built into it that allows

us to enroll more workers if needed; so there's that potential to expand to

other study - other districts for the study, which is really an important

consideration since we really can't predict what will happen next with the

Ebola epidemic.

Melissa Shapiro: Great, thank you. And before we open it for any questions on Ebola outbreak

in general, are there any other questions related to the vaccine trial?

Coordinator:

We do have a question come through, Joseph Conteh, your line's open.

Joseph Conteh:

Yes. I am clinical research associate - you know, in the United States, in Atlanta. And I've tried to see how best I can contribute and my question is, is there a specific database, a specific section that's created for clinical researchers?

Because I've tried to apply for some of those positions, and I haven't had feedback. I've also tried to attend the training in Alabama, and I haven't been successful so far. So is there somewhere - I can access that information or be considered for future or research opportunities in terms of Ebola? I am from Sierra Leone.

Alison Albert:

Melissa, is there anyone in the room that's handling questions around working for CDC around the Ebola response?

Melissa Shapiro: I'm sorry, can you repeat your question one more time?

Joseph Conteh:

The question is, is there a database or is there a particular department that deals specifically with clinical research professionals? Because I am a clinical research associate and have conducted trials in various disciplines. So I was just checking to see if there was a way that I could be of help to the current process that's ongoing.

Stacey Hoffman: Hi, this is - do you want to go ahead and address?

Jonta Williams:

This is Jonta calling from USAID. While we don't have a database that focuses specifically on clinical researchers, we do have kind of a broader database for individuals in the healthcare field who are interested in volunteering overseas in one of the affected countries.

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 29

And what I would recommend that you do is submit your information into that

system and indicate in one of the notes that you are in clinical research and

what your expertise is. What we do, is we then share all of that information

with our partners on the ground.

We have about 150 various partners that are working in each of the countries.

And they pull from that database according to their needs. So we can't

guarantee that a match would be made, but at least your information will be

filled and your expertise would be shared with the partners and they'll have -

have an opportunity to reach out to you.

You can also get to the webpage, the Center for International Disaster

Information webpage, <u>CIDI.org</u>. On that - the Ebola response page you can

see all of the partners that we have that are working on the ground in each of

the countries. And maybe reach out to them directly.

Like I said, there are about 150 so it's a large pool. We're not able to make

direct connections but through our database system and then maybe by

individually reaching out to some of these organizations you'll be able to

make a match.

Our USAID...

Joseph Conteh:

I believe that I'm in one of those databases. In fact, two of those databases and

maybe the needs have not yet been aligned with my current experience. But

I've had that in the system I think for the last five or six months.

I've never had feedback with regards to that. I believe, I've also worked with

a couple of other organizations including - that has to do with plague. So I

don't know why I haven't been contacted. But in any case, I will do what you say and see what comes out of it.

Jonta Williams: Sorry, I couldn't be more helpful.

Melissa Shapiro: Okay, thank you. Are there any other questions on the line?

Coordinator: I'm showing no further questions.

Melissa Shapiro: Okay, does anybody have any questions in general, not necessarily related to

the vaccine trials but anything about the Ebola outbreak?

Coordinator: And I'm showing no questions on the phone line coming through.

Melissa Shapiro: Okay, thank you. Well, before I wrap up I'd just like to remind any medical

professionals who are members of the Guinea diaspora here in the United

States who would like to volunteer in Guinea to email

EmergencyPartners@CDC.gov. Our next call in the series will be held on

Tuesday, April 28 at 2:00 pm Eastern.

And you can use the same call information that you used today to join this call. And if you happened to miss the previous call you can find the transcript, recording, and resources on CDC's Partnering with West African

Communities Call Series webpage. Today's call information will be posted to

this page in the next few weeks.

And if you would like to receive an email when these materials become available, please email us at EmergencyPartners@CDC.gov and we can add you to the mailing list.

Moderator: Melissa Shapiro 03-24-15/1:00 pm CT

Page 31

Again, if you have any additional questions for today's speaker, would like to suggest a topic for a future call, or have any other comments you'd like to share with CDC, please sends them to emergencypartners@cdc.gov.

Thank you again for joining us and I look forward to talking to you all again on April 28. And Operator, that concludes our call for today.

Coordinator:

Thank you. At this time you may disconnect your lines, have a great afternoon.

END